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Arizona State Board of Pharmacy

4425 W Olive Ave, Suite 140, Glendale, AZ 85302-3844
Web site: www.azpharmacy.gov
E-mail: info@azsbp.gov

Published to promote voluntary compliance of pharmacy and drug law.

Greetings

You have received the inaugural electronic Arizona State Board of Pharmacy *Newsletter*.

You probably received this first edition of the electronic version of the quarterly *Newsletter* either because your e-mail address was on file in our database or because you added your e-mail address to the circulation list on the National Association of Boards of Pharmacy®'s (NABP®) Web site at www.nabp.net. If you received this *Newsletter* via a forward from a friend or by some other means, please consider visiting the NABP Web site and "opt-in" by navigating to the state newsletters section, choosing Arizona, and adding your e-mail address to the mailing list to receive the electronic *Newsletter* in the future. Archived copies of the *Newsletters* are also available at www.azpharmacy.gov/newsletters.html. This new electronic version of the *Newsletter* will allow the Board to almost triple circulation while saving more than $20,000 in postage and printing expenses.

Board Web Site, E-mail Updates

The Web site address for the Arizona State Board of Pharmacy is changing from the familiar www.pharmacy.state.az.us to www.azpharmacy.gov. The primary reason for the change is to conform to state of Arizona Web page templates and to "brand" or "identify" the Arizona State Board of Pharmacy Web site as a government Web site (.gov) rather than a commercial one (.com). It is important to note that the Arizona Pharmacy Alliance Web site is www.azpharmacy.org and is identified as a non-profit organization by the ".org" domain name. The new Web site domain also allows the Board staff to obtain ".gov" e-mail addresses, which will make it easier for the public to contact individual staff because the addresses will conform to first initial then last name @azpharmacy.gov (eg, hwand@azpharmacy.gov). The previous personal and non-conforming individual e-mail addresses used by staff will be discontinued.

Refusal to Dispense Prescriptions

The Board is on record as supporting Senate Bill (SB) 1518 as twice amended. This bill, sponsored by Senator Carolyn Allen, et al, outlines the procedures a pharmacy permittee must have in place for its employees who object to dispensing certain prescriptions on religious or ethical grounds. The text of the bill and the amendments are available by searching for SB1518 on the Web site at www.azleg.state.az.us/.

This general topic reminds the Board that many pharmacists are confused about "medical scope of practice" and physician prescribing authority. The Board office regularly fields calls from medical doctors (MD) and doctors of osteopathy (DO) who specialize in cardiology or ophthalmology and complain that their prescriptions for drugs such as antibiotics are being denied by pharmacists. Assuming a valid patient/doctor relationship and a previous physical examination, such prescriptions are valid and may be dispensed as long as no drug interaction or other clinical reason not to dispense exists. On the other hand, pharmacists should refuse to dispense a prescription prescribed by an MD or DO for themselves or their immediate family if the prescription is for a controlled substance (CS) because this action is considered unprofessional conduct by the medical licensing boards.

Review of Generic Substitution and Prescription Blanks

A prescriber may indicate their intention to prevent generic substitution in any manner on their prescription blanks. The "two line signature blank," though no longer mandated, is still valid. If a prescriber signs on the **"do not substitute"** line, it qualifies as the prescriber indicating a prohibition of generic substitution by the pharmacist. This action does not prevent a pharmacist from contacting the prescriber for authorization to substitute generically, and any such authorization should be documented by the pharmacist in a routine manner. Please review Arizona Revised Statutes §32-1963.01(D) for clarification of this issue.

Look-Alike/Sound-Alike Dispensing Errors

Omacor® (omega-3-acid ethyl ester) for high triglyceride levels, and Amicar® (aminocaproic acid), a fibrinolysis inhibitor, are being confused and dispensed for each other. Please confirm all written and oral orders for these products.

FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben®, a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien®, a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis. An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a $175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working

with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- A table of contents for easy reference to detailed safety and efficacy information.
- The date of initial product approval, making it easier to determine how long a product has been on the market.
- A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

DEA Clarification on Class II Prescription Writing

On August 25, 2005, Drug Enforcement Administration (DEA) issued an interim policy statement,

> For a physician to prepare multiple prescriptions [for a (S)chedule II (CS)] on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a [S]chedule II CS. To do so conflicts with the provision of the [Controlled Substance Act] which provides: No prescription for a [CS] in [S]chedule II may be refilled.

Please be aware of this policy statement and contact an attorney for advice if you need help interpreting the new policy statement, which directly conflicts with an earlier DEA policy statement.

Compliance Reminders

All licensees (pharmacists, interns, and technicians) shall notify the Board of a change of address or employment within 10 days. A pharmacist-in-charge (PIC) shall notify the Board of such a change immediately and complete a CS inventory within 10 days. All permittees shall notify the Board of a change of location or remodel on the form provided by the Board office or obtained from the Board Web site.

It is the joint responsibility of the pharmacy permit holder and PIC to verify the license status of each pharmacist, intern, or technician before allowing the person to work in a pharmacy. Remember that out-of-state interns who work in Arizona for the summer need an Arizona intern license before working in an Arizona pharmacy; their home state intern license is not sufficient.

Disciplinary Actions – Board of Pharmacy (Actions Since January 2006 Newsletter)

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

John Alessi – Pharmacy Technician License #4058, Suspended one year, followed by three years Probation, CS Violations.

Vickie L. Wonder, RPh – Pharmacist License #9412, five year Probation and Pharmacists Assisting Pharmacists of Arizona (PAPA) contract, substance abuse.

Mustafa A. Maher, RPh – Pharmacist License #11070, suspended three months to one year, concurrent PAPA contract for five years, Probation until end of PAPA contract, CS violations. Prohibited from serving as a Preceptor or PIC during term of discipline.

Robert Preston Hooper, RPh – Pharmacist License #14739, five-year Probation, PAPA contract. Prohibited from serving as a Preceptor or PIC during term of discipline. CS violations.

Michelle Mai, RPh, – Pharmacist License #12319, Suspended one year, followed by two years Probation, $16,500 civil penalty, CS violations and drug rebate scheme involving fraudulent prescriptions. Prohibited from serving as a Preceptor or PIC during term of discipline.

Rob Hahn, RPh – Pharmacist License #10250, Suspended 60 days, followed by two years Probation; drug rebate scheme involving fraudulent prescriptions. Prohibited from serving as a Preceptor or PIC during term of discipline.

The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Harlan "Hal" Wand, RPh - State News Editor
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Larissa Doucette - Editorial Manager

ARIZONA STATE BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

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